phytate, a clay mineral, ethylenediaminetetraacetic acid (EDTA) and its sodium salts Na_2EDTA and Na_4EDTA, trisodium nitrilotriacetate monohydrate, trisodium nitriloacetate, pentasodium diethylenetriaminepentaacetate, trisodium N-hydroxyethyl-ethylenediaminetriacetate, citric acid, a citrate, a polyphosphate, a tripolyphosphate, an orthophosphate and a cellulose phosphate or (2) is a calcium-free, calcium binding compound derivable from a compound of (1) above by not more than one chemical reaction step.

REMARKS

1. Introduction

By this amendment, claims 15 and 22 are cancelled, 4-6, 14, 17-19 and 23 are amended, and 30-34 are added.

The amendment to main claim 14 introduced the "encapsulated form" limitation of claims 15 and 22, so they were cancelled as redundant.

These amendments are believed to render composition claim 14 allowable. Hence, dependent method claims 1-13 should be rejoined, pursuant to MPEP §821.04.

2. Prior Art Issues

2.1. Claims 14-19, 23-25, 28 and 29 stand rejected as anticipated by Schaumann, DE 1,255,466.

However, applicants' main claim has been amended per 15, which required that the compound for reducing the absorption of calcium be in encapsulated form. Schaumann does not disclose or suggest encapsulation.

2.2. Claims 14-19, 23-25, 28 and 29 are rejected under §102(e) as anticipated by Huzinec, USP 5,912,030.

Huzinec describes a comestible product adapted for extended release of flavor and sweetness. In essence, the flavor or sweetness additive is mixed with a carrier. This carrier may be a zeolite.

As noted, claim 14 has been amended to require that the active compound be encapsulation.

At col. 1, lines 37-47, Huzinec teaches away from encapsulation of additives:

> Encapsulation of additives such as flavors and sweeteners is time-consuming and expensive. In addition, the encapsulation process and parameters can change the character of the flavor (certain peaks present in the gas chromatographic spectrum of the flavor can be lost upon encapsulation) and some techniques of encapsulation can preclude the release of flavor in the final product. Further, encapsulation techniques can be used to prevent or retard the release of the additives, e.g., during the manufacturing process to prevent additive loss due to volatilization.

Huzinec teaches putting the flavor or sweetener in a zeolite carrier as an alternative to encapsulating them. Hence, Huzinec does not disclose encapsulating the zeolite.

2.3. Ashmead discloses urinary calculi treating compositions which comprise EDTA. However, the EDTA is not encapsulated.

2.4. Shinkyo JP 63056255 discloses a feed supplement which is a mixture of pieces of brown marine plants and "granules of zeolite". Ony the abstract has been made of record and it does not disclose encapsulation of the zeolite.

2.5. We would further note that none of the references are concerned with the prevention of parturient hypocalcemia in animals.

3. Enablement Issues

The elected claims are also rejected for lack of enablement. The Examiner suggests that the claims should further describe the composition, setting forth specific ratios and compositions.

Applicants have discovered that parturient hypocalcemia can be prevented by triggering the natural calcium regulating defense

mechanism of the animal. They have shown that hypocalcemia can be induced with EDTA (Ex. 1), zinc oxide (Ex. 2) and sodium aluminum zeolite A (Exs. 3 and 4), and that the latter can be used to prevent hypocalcemia in calving cows by first exposing the cows to the zeolite.

A large number of compounds are known to bind calcium; some of these are disclosed at page 5, line 31 to page 6, line 9. Once the utility of the zeolite was known, it was easy to identify alternative agents.

The appropriate dosages would, of course, depending both on the calcium-binding power of the compound, and on the physiology of the lactating animal in question (in particular, its calcium regulatory mechanisms).

It would not require undue experimentation to adjust the dose to a particular species of lactating animal. Some guidance is provided at page 5, lines 18-24:

> The amount of compound administered must be sufficient to obtain the preventive effect. It is preferred that the compound is administered in an amount of at least 10 g per animal per day depending on the body weight of the animal. More preferred at least 50 g of the compound is administered per day per animal. In particular in respect of zeolites and EDTA-compounds it may be preferred to administer at least 100 g per day per animal. Normally up to about 1000 g per day per animal is administered.

4. Definiteness Issues

4.1. We have replaced "peroral" (claim 14) with "oral".

4.2. The Examiner says that "suitable" is indefinite. The term is used in claim 14 ("suitable for oral administration"). This specific phrase is used in one or more claim of 1959 patents (see Exhibit A).

4.3. We have deleted "and a calcium-free derivative of any such compounds" from claims 4-6, 17-19 and 23. In new claims 32-34, we explore alternatives to the "derivatives" language. Claim 32(2) covers use of substances in fact derived by one or more

chemical reaction steps from a compound of 32(1). Claims 33 and 34 cover only those derivatives which are derivable by not more than two (33) or not more than one chemical reaction steps (34).

4.4. Claim 23 is revised to recite "a fat, a soap, a stearate..."

4.5. The Examiner's comments on "membrane material" are not understood. It is not necessary that the chemical nature of the membrane material be specified. What is important is its property, as recited in 24. Breadth is not indefiniteness.

4.6. The Examiner's comments on "orthophosphates" are not understood. What is wrong with this term?

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with markings to show changes made".

Respectfully submitted,

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Enclosure
-Exhibit A

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims:

Claims 15 and 22 have been cancelled.

Claims 4-6, 14, 17-19 and 23 have been amended as follows:

4 (amended). The method according to claim 3 wherein the calcium-binding compound is selected from the group consisting of oxalic acid, sodium oxalate, phytic acid, a phytate, a clay mineral [including zeolite], ethylenediaminetetraacetic acid (EDTA) and its sodium salts Na_2EDTA and Na_4EDTA, trisodium nitrilotriacetate monohydrate, trisodium nitriloacetate, pentasodium diethylenetriaminepentaacetate, trisodium N-hydroxyethylethylene-diaminetriacetate, citric acid, a citrate, a polyphosphate, a tripolyphosphate, an orthophosphate and a cellulose phosphate [and a calcium-free derivative of any such compounds].

5 (amended). The method according to claim 4, wherein the calcium-binding compound is selected from the group consisting of zeolites, ethylenediaminetetraacetic acid (EDTA) and its sodium salts Na_2EDTA and Na_4EDTA, a polyphosphate, a tripolyphosphate, an orthophosphate and a cellulose phosphate [and a calcium-free derivative of any such compounds].

6 (amended). The method according to claim 5, wherein the calcium-binding compound is [selected from the group consisting of] syntectic sodium aluminosilicate zeolite [A] type A [and a calcium-free derivative of any such compounds].

14 (amended). A composition for preventing parturient hypocalcemia in an animal, comprising, in a suitable form for [peroral] oral administration, at least one compound which reduces the absorption of calcium for the drinking water and/or from the ration of said animal, wherein the compound is in encapsulated form.

17 (amended). The composition according to claim 16, wherein the calcium-binding compound is selected from the group consisting of oxalic acid, sodium oxalate, phytic acid, a phytate, a clay mineral [intluding zeolite],

ethylenediaminetetraacetic acid (EDTA) and its sodium salts Na_2EDTA and Na_4EDTA, trisodium nitrilotriacetate monohydrate, trisodium nitriloacetate, pentasodium diethylenetriaminepentaacetate, trisodium N-hydroxyethyl-ethylenediaminetriacetate, citric acid, a citrate, a polyphosphate, a tripolyphosphate, an orthophosphate and a cellulose phosphate [and a calcium-free derivative of any such compounds].

18 (amended). The composition according to claim 17, wherein the calcium-binding compound is selected from the group consisting of a clay mineral [selected from zeolite], ethylenediaminetetraacetic acid (EDTA) and its sodium salts Na_2EDTA and Na_4EDTA, a polyphosphate, a tripolyphosphate, an orthophosphate and a cellulose phosphate [and a calcium-free derivative of any such compounds].

19 (amended). The composition according to claim 18, wherein the calcium-binding compound is <u>a clay mineral, and the clay mineral is a zeolite</u> [selected from the group consisting of a clay mineral selected from zeolite and a calcium-free derivative of any such compounds].

23 (amended). The composition according to claim 14 or 22 where the compound is encapsulated by a compound selected from the group consisting of a fat, [a non-calcium derivative of a fat such as] a soap, [and] a stearate, a protein, a polysaccharide, a cellulose, a gum, a glycol, gelatine and a derivative of any such compound.

Claims 30-34 have been added.

Exhibit A

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PATENT FULL TEXT AND IMAGE DATABASE

Searching All Years...

Results of Search in All Years db for:
ACLM/"suitable for oral administration": 1959 patents.
Hits 1 through 50 out of 1959

Next 50 Hits

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Refine Search aclm/"suitable for oral administration"

	PAT. NO.	Title
1	6,297,229	Use of ursodeoxycholic acid to treat nonalcoholic steatohepatitis
2	6,296,892	Beverages for enhanced physical performance
3	6,294,520	Material for passage through the blood-brain barrier
4	6,294,195	Orally administrable opioid formulations having extended duration of effect
5	6,294,192	Triglyceride-free compositions and methods for improved delivery of hydrophobic therapeutic agents
6	6,291,462	Oral medicinal preparations with reproducible release of the active ingredient gatifloxacin or its pharmaceutically suitable salts or hydrates
7	6,288,091	Antiherpes virus compounds and methods for their preparation and use
8	6,287,600	Stabilized pharmaceutical composition of a nonsteroidal anti-inflammatory agent and a prostaglandin
9	6,284,268	Pharmaceutical compositions containing an omega-3 fatty acid oil
10	6,280,770	Microemulsions as solid dosage forms for oral administration
11	6,280,751	Essential oil composition
12	6,280,744	Use of inorganic aerogels in pharmacy
13	6,277,882	Utilization of alkyl hydrogen fumarates for treating psoriasis, psoriatic arthritis, neurodermatitis and regional enteritis
14	6,274,599	Cisapride extended release
15	6,274,595	Compositions for treating infection using optically pure (S)-lomefloxacin
16	6,274,158	Treatment with recombinant human erythropoietin of bleeding in patients with normal and abnormal hemostasis
17	6,271,262	Metalloproteinase inhibitors
18	6,271,246	Pharmaceutical compositions for managing scalp conditions
19	6,271,230	Use of NK-1 receptor antagonists for treating cognitive disorders
20	6,270,798	Lozenge for the modified releasing of active substances in the gastrointestinal tract
21	6,268,374	Uracil reductase inactivators

22 6,265,449 Aqueous compositions comprising ranitidine and LCMT sucrose

23 6,265,420 Use of nitric oxide scavengers to treat side effects caused by therapeutic administration of sources of nitric oxide

24 6,264,985 Laminated tablet with pointed core

25 6,262,316 Oral preparation for the prophylactic and therapeutic treatment of Helicobacter sp. infection

26 6,262,086 Pharmaceutical unit dosage form

27 6,262,019 Method of treatment of glutathione deficient mammals

28 6,261,601 Orally administered controlled drug delivery system providing temporal and spatial control

29 6,261,599 Melt-extruded orally administrable opioid formulations

30 6,261,565 Method of preparing and using isoflavones

31 6,258,847 Use of 2-mercaptoethanolamine (2-MEA) and related aminothiol compounds and copper(II)-3,5 di-isopropyl salicylates and related compounds in the prevention and treatment of various diseases

32 6,258,805 Pyrroloazepine derivatives

33 6,258,375 Antibacterial phosphoinositides

34 6,255,296 Composition and method for treating a patient susceptible to or suffering from a cardiovascular disorder or disease

35 6,254,887 Controlled release tramadol

36 6,254,882 Methods and compositions for treating pulmonary disorders using optically pure (S)--salmeterol

37 6,251,927 Methods for treatment of sickle cell anemia

38 6,251,427 Pharmaceutical capsule compositions containing loratadine and psuedoephedrine

39 6,248,767 Formulation of sulfonamides for treatment of endothelin-mediated disorders

40 6,248,327 Modulation of endothelial cell surface receptor activity in the regulation of angiogenesis

41 6,245,817 NPY5 receptor antagonists and methods for using same

42 6,245,805 Method, compositions and kits for increasing the oral bioavailability of pharmaceutical agents

43 6,245,354 Drug delivery system using galactoxyloglucan

44 6,242,485 Endothelin antagonist

45 6,242,478 Five member ring sulfenate esters and thiosulfinate esters

46 6,242,431 Method for treating liver dysfunction

47 6,242,429 Arabinosyladenine derivatives

48 6,239,141 Trovafloxacin oral suspensions

49 6,238,698 Oral preparation containing at least one active pharmaceutical substance in a matrix capable of swelling in an aqueous medium

50 6,235,733 Oral liquid formulations of benzoxazinones HIV reverse transcriptase inhibitors

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